

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Katherine Gordon et al.  
Serial No.: 07/839,194  
Confirmation No.: 6108  
Filed: February 20, 1992  
For: TRANSGENIC ANIMALS SECRETING DESIRED PROTEINS INTO MILK  
Examiner: D. A. Montanari  
Art Unit: 1632

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I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: March 7, 2011

Signature: /Heather A. McLennand/ (Heather A. McLennand)

**PETITION TO WITHDRAW A RECORDED TERMINAL DISCLAIMER**  
**UNDER 37 C.F.R. § 1.182**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant respectfully requests that the Terminal Disclaimer filed on August 16, 2010 (the "Terminal Disclaimer") in the above-referenced case be withdrawn. A recorded terminal disclaimer may be withdrawn before the application in which it is filed issues as a patent. MPEP § 1490 at 1400-118 ("VII. WITHDRAWING A RECORDED TERMINAL DISCLAIMER"). The above-referenced application has not yet issued as a patent, although the issue fee is due March 30, 2011 in response to the Examiner's Notice of Allowance of December 30, 2010.

Without admitting the propriety of the rejection, the Terminal Disclaimer was originally filed "to serve the statutory function of removing" the Examiner's nonstatutory obviousness-type double patenting rejection over claims 1-5 of U.S. Patent No. 6,727,405 (the '405 Patent). MPEP § 804.02 at page 800-32, column 1 (A terminal disclaimer "is not an admission of the propriety of the rejection"). In the Notice of Allowance, however, the Examiner indicated that

upon further review no double patenting existed with the pending claims over the claims in the '405 Patent due to the safe-harbor of 35 U.S.C. § 121.

The Examiner stated that the '405 Patent claims priority from Application No. 06/849,815 in which a Restriction Requirement was issued restricting between two groups: 1) the DNA construct comprising a mammalian milk serum protein promoter and 2) a transgenic non-human mammal comprising said construct. The Examiner concluded that no double patenting existed between the instant claims and the claims of the '405 Patent because the DNA construct was restricted from the transgenic non-human mammal<sup>1</sup>. See *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563 (Fed. Cir. 1996). ("However, even if such consonance is lost, double patenting does not follow if the requirements of § 121 are met or if the claims are in fact patentably distinct.") (emphasis added).

"If timely requested, a recorded terminal disclaimer may be withdrawn before the application in which it is filed issues as a patent . . . ." MPEP § 1490 at 1400-118. Because the Examiner has indicated that a terminal disclaimer is no longer required to remove the obviousness-type double patenting rejection, and this petition has been timely filed before the patent issues, Applicant requests withdrawal of the terminal disclaimer.

Please charge our credit card in the amount of \$400.00 covering the fee set forth in 37 CFR 1.17(f). The Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 23/2825, under Docket No. G0744.70042US07 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: March 7, 2011

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<sup>1</sup> The claims of the instant application are shown in Attachment A, while the claims of the '405 Patent are shown in Attachment B.

**ATTACHMENT A**

Allowed Claims of Instant Application

1. A DNA construct comprising a gene encoding a protein, said gene being under transcriptional control of a mammalian milk protein promoter sequence which does not naturally control transcription of said gene, said DNA construct further comprising DNA encoding a peptide enabling secretion of said protein.
2. The DNA construct of claim 1, wherein said secretion enabling peptide comprises a secretion signal peptide which is cleaved from said secretion protein.
- 3-4. (Canceled)
5. The DNA construct of claim 1, wherein said DNA encoding a peptide enabling secretion of said protein is the signal encoding sequence naturally associated with said gene encoding said protein.
6. The DNA construct of claim 1, wherein said DNA encoding a peptide enabling secretion of said protein is the signal encoding sequence naturally associated with said mammalian milk protein promoter.
7. The DNA construct of claim 1, wherein said DNA sequence includes a transcriptional stop sequence.
8. The DNA construct of claim 7, wherein said stop sequence comprises the SV40 virus polyadenylation site.
- 9-10. (Canceled)

11. The DNA construct of claim 1, wherein said gene encodes human tissue plasminogen activator or hepatitis B surface antigen.

12-15. (Canceled)

16. The DNA construct of claim 1, wherein said milk protein is a milk serum protein.

17. The DNA construct of claim 16, wherein said milk serum protein is alpha-lactalbumin.

18-29. (Canceled)

30. The DNA construct of claim 1, wherein the mammalian milk protein promoter sequence is the sequence of a milk serum protein promoter.

31. The DNA construct of claim 30, wherein the milk serum protein promoter is an  $\alpha$ -lactalbumin promoter.

32. The DNA construct of claim 30, wherein the milk serum protein promoter is a  $\beta$ -lactoglobulin promoter.

33. The DNA construct of claim 1, wherein the mammalian milk protein promoter sequence is the sequence of a casein protein promoter.

**ATTACHMENT B**

Issued Claims of U.S. Patent No. 6,727,405

1. A non-human mammal whose genome comprises a DNA construct comprising a whey acidic protein promoter operably linked to a DNA sequence encoding a heterologous protein, wherein said construct further comprises a DNA sequence encoding a secretory peptide operatively linked to said DNA sequence encoding a heterologous protein, wherein said mammal is selected from the group consisting of mouse, sheep, pig, goat and cow, and wherein said heterologous protein is expressed in the milk of the mammal.

2. A method of producing a protein comprising the steps of:

- (a) providing an adult, female non-human mammal whose genome comprises a DNA construct comprising a whey acidic protein promoter operably linked to a DNA sequence encoding a heterologous protein, wherein said construct further comprises a DNA sequence encoding a secretory peptide operatively linked to said DNA sequence encoding a heterologous protein, wherein said mammal is selected from the group consisting of mouse, sheep, pig, goat and cow,
- (b) inducing lactation in said mammal, thereafter
- (c) collecting milk from said lactating mammal, and
- (d) isolating said heterologous protein from said collected milk.

3. The method of claim 2, wherein the mammal of step (a) was developed from a fertilized ovum comprising said DNA construct.

4. The method of claim 2, wherein said protein is biologically active human tissue plasminogen activator.

5. A DNA construct comprising (i) a whey acidic protein promoter operably linked to a DNA sequence encoding a heterologous protein, and wherein said construct further comprises (ii) a DNA sequence encoding a secretory peptide operatively linked to said DNA sequence encoding (iii) a heterologous protein.

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